

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in January 2001.

New Approvals

ANADA Number: 200-292

Pioneer Product: 140-439
Trade Name: Iversol Liquid for Horses
Ingredients: Ivermectin
Sponsor: Med-Pharmex, Inc.
Approval Date: December 7, 2000
Status: Prescription only
Route: Oral
Species: Horses
Drug Form: Liquid (solution)
Concentration: 1%
Indications: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

21CFR 520.1195

NADA Number: 141-177

Trade Name: Mometamax[™] Otic Suspension
Ingredients: Gentamicin sulfate, mometasone furoate monohydrate, clotrimazole
Sponsor: Schering-Plough Animal Health
Approval Date: December 5, 2000
Status: Prescription only
Route: Topical
Species: Dogs
Drug Form: Liquid (suspension)
Concentration: 3 mg gentamicin, 1 mg mometasone, and 10 mg clotrimazole per gram
Indications: For the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin.
Patent Number: 4,472,393 Expiration date: September 18, 2001
5,502,222 June 1, 2014
5,616,742 May 22, 2015
5,750,745 May 30, 2015
5,886,200 June 25, 2017
6,127,353 October 3, 2017
Exclusivity: 3 years

21CFR 524.1044h

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-149

Trade Name: Deccox[®] plus Rumensin[®] plus Tylan[®]
Ingredients: Decoquinatate, monensin, tylosin
Sponsor: Alpharma, Inc.
Approval Date: November 16, 2000
Status: Over-the-counter
Route: Oral
Species: Growing-finishing cattle being fed in confinement for slaughter
Drug Form: Type A Medicated Articles to make three-way combination Type B and C medicated feeds.
Concentration: Decoquinatate: 27.2 grams of decoquinatate activity per pound of Type A Medicated Article
Monensin: 20, 30, 45, 60, 80, or 90.7 grams of monensin activity per pound of Type A Medicated Article
Tylosin: 10, 40 or 100 grams of tylosin activity per pound of Type A Medicated Article
Indications: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for improved feed efficiency and for reduction of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*.
Tolerance: CFR 556.170 Decoquinatate: A tolerance of 2 ppm in tissues other than skeletal muscle and 1 ppm in skeletal muscle has been established for residues of decoquinatate.
CFR 556.420 Monensin: A tolerance of 0.05 ppm in the edible tissues has been established for residues of monensin.
CFR 556.740 Tylosin: A tolerance of 0.2 ppm in uncooked fat, muscle, liver, and kidney has been established for residues of tylosin.
Withdrawal: Zero days

21CFR 558.195, 558.355, and 558.625

NADA Number: 141-174

Trade Name: Aicarexx[™]
Ingredients: Ivermectin
Sponsor: Blue Ridge Pharmaceuticals, Inc.
Approval Date: December 5, 2000
Status: Prescription only
Route: Topical
Species: Cats, kittens
Drug Form: Liquid (suspension)
Concentration: 0.01%
Indications: For the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens four weeks of age or older.
Patent Number: 4,761,288 Expiration date: August 2, 2005
4,897,269 January 30, 2007
4,937,078 June 26, 2007
Exclusivity: 3 years

21CFR 524.1195 and 510.600

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Change of Sponsor

NADA Numbers: 065-110 and 065-498

From: Pfizer, Inc.
To: Phoenix Scientific, Inc.
3915 South 48th St. Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457
Drug labeler code: 059130

Addition of Sponsor

Blue Ridge Pharmaceutical, Inc.
4249-105 Piedmont Pkwy.
Greensboro, NC 27410
Labeler code: 065274

Suitability Petition Action

Number:	00P-1519/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Heartgard-30 [®]), Merial Ltd., NADA 140-886 by the following characteristics: Ivermectin generic is a compressed 'chewable' tablet and Heartgard-30 [®] is an 'extruded chewable' tablet.
Action:	Approved on December 7, 2000
Number:	00P-1600/CP1
Sponsor:	Buford Biomedical, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan [®] Paste), Merial Ltd., NADA 134-314 by the following characteristics: Ivermectin generic is a 6.8% powder formulation to be administered in the feed.
Action:	Filed on November 3, 2000
Number:	00P-1655/CP1
Sponsor:	Highland VetPharma, LLC
Petition:	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone (Phenylbute [®]), Phoenix Scientific, Inc., NADA 091-818 by the following characteristics: The generic product will consist of a different dosage form ('chewable' tablet) from the pioneer.
Action:	Approved on January 29, 2001